

REMARKS

Claims 1 and 6-12 were pending in the application. New claims 35-41 have been added. Accordingly, upon entry of the amendments presented herein, claims 1, 6-12 and 35-41 will be pending.

New claim 35 is drawn to a method for eliminating a target cell or antigen from the circulatory system of a subject comprising, administering to the subject a composition comprising monomeric IgA. Support for new claim 35 can be found throughout the application as filed, for example, page 2, line 20 through page 3, line 2; page 3 (lines 12-15); page 13 (lines 1-11); and in original claims 1-3.

New claim 36 specifies that the target cell is a cancer cell. Support for new claim 36 can be found throughout the application as filed, for example, at page 3 (lines 26-32); and page 14 (lines 19-25) and in original claim 7.

New claim 37 specifies that the target antigen is a bacteria, a virus, and a fungus. Support for new claim 37 can be found throughout the application as filed, for example, at page 3 (lines 12-15); page 3 (lines 33-37); page 12 (lines 33-35); page 13 (lines 8-11); page 14 (lines 26-33); and in original claim 8.

New claims 38-39 recite an additional step of administering to the subject a cytokine (*i.e.*, GM-CSF, IL-6, IL-1 β , IL-8, and TNF- α) which increases expression of Fc α RI on Kupffer cells. Support for new claims 38-39 can be found throughout the application as filed, for example, page 3 (lines 18-22); page 13 (lines 14-18); and in original claims 9 and 10.

New claims 40-41 specify that the composition is administered by injection or intravenously. Support for new claims 40-41 can be found throughout the application as filed, for example, in original claims 11 and 12.

No new matter has been added. Any amendment and/or cancellation of the claims should in no way be construed as an acquiescence to any of the Examiner's rejections and was performed solely in the interest of expediting prosecution of the application. Applicants reserve the right to pursue the claims as originally filed in this or a separate application(s).

Acknowledgment of the Examiner's Withdrawal of Certain Rejections and Objections

Applicants gratefully acknowledge the Examiner's withdrawal of the following rejections: (a) the previous objection to claim 34 under 37 CFR 1.75(c) as being of improper dependent form; (b) the previous objection to the specification as failing to provide proper antecedent basis for the term "non-natural recombinant genetic fusion; (c) the previous rejection of claims 1, 6-12 and 34 under 35 U.S.C. 112, first paragraph as introducing new subject matter; (d) the previous rejection of claims 1, 6-12 and 34 under 35 U.S.C. 112, first paragraph for lacking a fully enabling disclosure; (e) the previous rejection of claim 34 under 35 U.S.C. 102(b) as being anticipated by van Spriel *et al.* (*Journal of Infectious Diseases*, 179(3):661-669, 3/3/1999); and (f) the previous rejection of claim 34 under 35 U.S.C. 102(e) as being anticipated by Deo *et al.* (U.S. Patent No.: 5,922,845).

Rejection of Claims 1 and 6-12 Under 35 U.S.C. § 112, First Paragraph – Written Description and New Matter

Claims 1 and 6-12 are rejected under 35 U.S.C. § 112, first paragraph, as introducing new matter and containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, has possession of the claimed invention. Specifically, the Examiner asserts that the specification lacks support for methods of treating cancer and infections (*i.e.*, bacterial, viral and fungal infections) using monomeric IgA and an antibody (or fragment thereof) which specifically binds to the target cell (*i.e.*, cancer cell or bacterial, viral or fungal antigen).

Applicant respectfully traverses this rejection. Contrary to the Examiner's assertion, it is clear from the specification that the invention is based on the discovery that monomeric (serum) IgA binds to FcαR-expressing cells and causes elimination (*e.g.*, phagocytosis) of antigens or target cells bound to monomeric IgA (see, for example, the first paragraph of the Summary of the Invention at page 2, lines 20-26). Accordingly, the very focus of the present application is to harness this feature of monomeric IgA to eliminate a target cell (*i.e.*, a cancer cell) or antigen (*i.e.*, bacteria, virus or fungus) from the circulatory system of a subject, as currently claimed. Specifically, support for the presently claimed methods is available at least, for example, at page 2, line 20 through page 3, line 32; page 12 (lines 33-35); page 13 (lines 1-21); page 14 (lines 19-33); and in original claims 1-3 and 7-8. Indeed, it is clear that the use of monomeric

IgA for treating cancer and infections (*i.e.*, bacterial, viral and fungal infections) is not only clearly and explicitly contemplated within the four corners of the present specification, but also is the central aspect of the invention.

In view of the foregoing, Applicants respectfully request that the Examiner reconsider and withdrawn this rejection.

Rejection of Claims 1 and 6-12 Under 35 U.S.C. § 112, First Paragraph – Enablement

Claims 1 and 6-12 are rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement. The Examiner acknowledges that the specification is

enabling for a method of eliminating a target cell of antigen from the circulatory system of a subject comprising administering monomeric (serum) IgA or administering a bispecific antibody comprising an antibody fragment that binds FcαRI outside the natural ligand being domain and an antibody fragment that binds a target cell or antigen, wherein the antibody fragments of the bispecific antibody are linked via chemical conjugation or by recombinant genetic fusion (emphasis added)

However, the Examiner asserts that the specification

does not reasonably provide enablement for a method of eliminating a target cell or antigen from the circulatory system of a subject comprising administering monomeric IgA and an agent/antibody/antibody fragment that binds a target cell or antigen as embraced by the claims.

As a preliminary matter, Applicants respectfully note that new claims 35-41 are drawn to an embodiment, which as acknowledged by the Examiner, is enabled. Specifically, new claim 35 (and claims dependent therefrom) is drawn to ***a method for eliminating a target cell or antigen from the circulatory system of a subject comprising administering to the subject a composition comprising monomeric IgA***. Accordingly, new claims 35-41 should be in condition for allowance.

With respect to the Examiner's rejection of claims 1 and 6-12, Applicants respectfully traverse. Contrary to the Examiner's assertion, Applicants do, indeed, enable a method of eliminating a target cell or antigen from the circulatory system of a subject by administering monomeric IgA and an agent (*e.g.*, an antibody or fragment thereof) that binds a target cell or antigen, as discussed in detail above. Specifically, as discussed above, Applicants teach that monomeric (serum) IgA binds to FcαR-expressing cells and causes elimination (*e.g.*, phagocytosis) of antigens or target cells bound to monomeric IgA (see, for example, the first

paragraph of the Summary of the Invention at page 2, lines 20-26). As discussed above, the very focus of the present application is to harness this feature of monomeric IgA to eliminate a target cell (*i.e.*, a cancer cell) or antigen (*i.e.*, bacteria, virus or fungus) from the circulatory system of a subject, as currently claimed. Applicants provide ample guidance to enable one of ordinary skill in the art to make and use the claimed invention, without undue experimentation (see, for example, page 2, line 20 through page 3, line 32; page 12 (lines 33-35); page 13 (lines 1-21); page 14 (lines 19-33); and original claims 1-3 and 7-8).

Thus, based on the teachings in the specification, as well as knowledge available in the art, the ordinarily skilled artisan would be able to make and use the claimed invention using only routine experimentation. Accordingly, Applicants respectfully request that the Examiner reconsider and withdrawn this rejection.

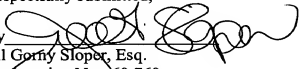
CONCLUSION

In view of the foregoing amendments and arguments, reconsideration and withdrawal of all the rejections and allowance of this application with all pending claims are respectfully requested. If a telephone conversation with Applicants' Attorney would expedite the prosecution of the above-identified application, the Examiner is urged to call (617) 227-7400.

Applicants believe no additional fee is due with this response. However, if an additional fee is due, please charge our Deposit Account No. 12-0080, under Order No. MXI-170RCE2 from which the undersigned is authorized to draw.

Dated: October 31, 2007

Respectfully submitted,

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